"Business Practice Guidelines" to Advance Translational Research Activities involving Multiple Institutions

INDEMNIFICATION AND INSURANCE ISSUES AND PRACTICE GUIDELINES

Overview

Indemnification and insurance are two business issues that can effect the development of research collaborations. Indemnification describes the obligation of one party to be responsible for liability incurred by another party. Insurance is a mechanism for paying for liability. While we believe that the establishment of uniform indemnification language for different types of research arrangements can address many of the current problems posed by indemnification, we believe that access to insurance coverage is a developing problem that cannot be fully addressed at present.

Indemnification

Are disputes on indemnification creating obstacles to research activity?

Short Answer:

Yes. Organizations currently take different positions with regard to contractual indemnification provisions. These differences can be attributed to varying perceptions of risk, cost-benefit analysis, ability to indemnify under law, and value placed on contract language. These different positions create obstacles when research sponsors, sites and investigators negotiate indemnification language.

Discussion:

Some sites view indemnification as a "neutral" provision if the contract provision simply confirms that each party is responsible for its own negligence. In these situations, the initial party is required to indemnify another party only for liability solely caused by the initial party. The initial party does not assume any responsibility for the other party's separate negligence.

Other sites view indemnification as an important tool to shift liability and risk. Such risk-shifting is necessary based on the site's cost-benefit analysis with regard to the research project. The site will compare the risk and liability of the research project with the benefits derived from the research. For example, a party may decide that it will participate in research only if the sponsoring organization will indemnify it for any liability arising out of the work, including liability resulting from the indemnified parties own negligence.

Guiding Principles and Recommendations:

1. Focus on Collaborative Arrangements. Research arrangements should reflect true collaboration between the participants rather than a "fee-for-service" subcontract arrangement. By this we mean that the participants should share benefits, such as intellectual property, publicity and public recognition, participation in translational work, and economic return. This true collaboration allows both organizations to take on the risk which is shared by mutual indemnification language in the research agreement.

2. Equitable Indemnification Obligations. The provision of liability coverage and indemnification should be equitable based on a site's degree of benefit.

2.1 Mutual Indemnification. If the research arrangement is fully collaborative and the benefits mutual (a partnership approach), then equal and mutual cross-indemnification may be appropriate. Each party would indemnify the other for liability caused by the indemnifying party's acts or omissions.

2.2 Unilateral Indemnification. If research arrangements are purely fee-for-service arrangements where the primary site owns the entire project and all benefits, the primary site should indemnify the secondary site for all liability that the secondary site might incur, regardless of the cause of the liability. In this situation, there is often an exception to the primary site's indemnification obligation for liability to the secondary site cause by the secondary site's intentional acts or gross negligence.

2.3 Hybrid Indemnification. If research arrangements are collaborative and the benefits are unequal, the sites should pursue equitable (though not necessarily equal) indemnification that tracks the respective benefits to the parties.

3. Develop Model Indemnification Language. Establish a common standardized indemnification language for mutual indemnification (for fully collaborative arrangements) and unilateral indemnification (for fee for service style arrangements). See attached language.

Sample Language on Indemnification

Mutual Indemnification (for project with equal benefits):

Each party shall indemnify and save harmless the other for, from and against all actions, liabilities, losses, damages, claims and demands whatsoever, including costs, expenses and attorney's fees resulting from or claimed to have resulted from any intentional or negligent acts or omissions of the indemnifying party or its employees or agents engaged in the work under this Agreement at the time of the event or occurrence upon which such actions, claims or demands are based. Where both PARTY 1 and PARTY 2, including their respective employees or agents, participated in the liability causing event, each party shall contribute to the common liability a pro rata share based upon its relative degree of fault.

Sponsor Indemnification of Site (Clinical Research Study – human subjects; pure fee for service arrangement):

Sponsor agrees to indemnify, defend and hold harmless the Institution, its affiliated hospitals, trustees, officers, agents, staff, employees, IRB and the Principal Investigator (and any co/sub-Investigator), including his or her trustees, officers, agents, staff and employees (collectively "Indemnitees" or individually as an "Indemnitee") against any demands, claims, suits or judgments made or instituted against Indemnitees, by reason of injury (including death) to any person or damage to property, arising, in whole or in part, out of the implementation of the Study protocol (including Sponsor's written instructions), the Study drug, Study device, or the Sponsor's use/disclosure of patient information.

However, Sponsor will have no liability to an Indemnitee for loss or damage to the extent resulting from an Indemnitiee's: (1) failure to adhere to material terms of the Sponsor's Protocol or Sponsor's written instructions concerning use of the Study drug or device, (2) failure to comply with applicable FDA or other U.S. government regulations, or (3) negligence or willful misconduct by the Indemnitee, where such negligence or willful misconduct is finally determined by a judgment of a court of competent jurisdiction.

If any Indemnitee claims that it is entitled to the benefits to be provided by Sponsor under this Section, Sponsor will provide such benefits for the Indemnitee unless and until there is a final judicial determination by a court of competent jurisdiction that the Indemnitee is not entitled to such benefits.

In regards to any claim, suit or cause of action described above, Indemnitees shall have the right to be present at any pre-trial litigation, including but not limited to negotiations, mediation, arbitration as well as any trial and appeal arising therefrom, and Sponsor shall provide them with adequate notice of such. Sponsor shall not admit liability on behalf of any Indemnitee without such Indemnitee's prior written consent. Sponsor may not agree to a settlement which may result in a report to a state licensing board or the National Practitioner Data Bank, without Indemnitees' advance written consent.

Sponsor agrees to indemnify, defend and hold harmless the Indemnitees against any demands, claims, suits or judgments made or instituted against Indemnitees, arising out of the allegation that Sponsor's furnishing or supplying Indemnitees with (or the Indemnitees' use of) products, goods, protocol instructions, practices or methods under this Agreement constitute an infringement of any patent, copyright, trademark, trade name, trade secret or other proprietary or contractual right of any third party.

Insurance

Is insurance availability or cost an obstacle to clinical trial activity?

Short Answer:

At present, access to insurance for pre-clinical and clinical trial research activities does not appear to be preventing research projects. Rarely are studies delayed or rejected due to the insurance status of a party. However, the workgroup identified the following concerns:

1. Community physicians engaged in clinical trial work may assume that they have coverage for this activity under their existing medical malpractice coverage when the research activity may be excluded from that coverage;

2. Smaller research organizations may not have ready access to necessary insurance; and

3. Community physicians who want to split their time between clinical practice and pre-clinical or bench research activities may be discouraged from research activity if they cannot secure a reduced premium for their part time clinical practice.

Discussion:

1. Access to Research Coverage for Independent Physicians and Smaller Research Organizations. Large healthcare organizations and state academic institutions have policies of insurance, programs of self-insurance or may be insured through state programs. As a result, these organizations can provide coverage for employed physicians. Access to coverage for non-employed physicians through these insurance policies or self insurance may be more difficult to arrange.

Community physicians engaged in clinical trial work may assume that their existing medical malpractice coverage includes the clinical trial activity and this may not be the case. If their malpractice policies exclude research activity, research sponsors, sites and physician investigators need to identify alternative sources of coverage.

Finally, the degree to which small research organizations can secure adequate insurance coverage is unclear. We believe that if these organizations and physicians do not have access to adequate coverage at a reasonable rate, research collaborations may be delayed or impeded. Where one party is not adequately insured, any other party with proper insurance coverage will bear a greater financial burden in the event of a claim or legal cause of action.

2. Availability of "Part Time" Clinical Coverage at a Reasonable Price. Even where research coverage is available, a physician who maintains a part-time clinical practice while engaged in pre-clinical or bench research activities may have to pay a full premium for clinical coverage because "part time" clinical coverage may not be available. The lack of "part time" clinical coverage at a reasonable price may discourage some community physicians from participating in research activity.

Guiding Principles and Recommendations:

1. Ongoing Review of Availability of Coverage. Because our assessment of insurance issues was based on limited information, we recommend that a business practices consortium monitor this issue and, if necessary, investigate the degree to which access to research coverage and "part time" clinical malpractice coverage may impede research activities. If research demonstrates that these are impediments to collaborative research activities, the group can explore specific

solutions, such as group purchasing arrangements, the creation of private risk sharing entities or state sponsored risk pool support.

2. Interim Step: Resources and Work with Existing Carriers. As an interim step, we recommend that the consortium maintain a list of commercial carriers providing research coverage and make the list available to physicians and organizations seeking this coverage. The group could also approach medical malpractice carriers to encourage them to incorporate clinical trial coverage in standard malpractice policies and to make clinical malpractice coverage available on a "part time" premium basis when the physician can demonstrate separate coverage for the research activity. The group may also wish to address the relationship between indemnification and insurance, particularly in situations where an insurer excludes from coverage liability assumed by contract.